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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,772	07/31/2002	Malcolm Roy Brandon	78870/00004	7473

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,772	BRANDON ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *16-19,31-33 and 37-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,20-30 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 filing of PCT/AU00/00408, filed May 5, 2000, which claims benefit to foreign applications PQ 0202, filed May 6, 1999, PQ 203, filed May 6, 1999, PQ 0204, filed May 6, 1999, and PQ 1361, filed June 30, 1999.

Applicants' amendment filed November 28, 2005 has been received and entered. The specification has been amended. Claims 1 and 34 have been amended. Claims 35-40 have been added. Claims 1-40 are pending.

Election/Restriction

Applicant's election of Group I, in the reply filed on April 18, 2005 was acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected invention of group 1 (claim(s) 1-15, 20-30 and 34) were drawn to a method of preparing a reprogrammed diploid cell comprising introducing diploid nuclear material into a recipient cell, then removing the recipient cell's nuclear material to result in a reprogrammed diploid cell (see office action mailed March 16, 2005). New claims 35-40 are encompassed by the elected invention.

Claims 1-40 are pending. Claims 16-19, 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable

generic or linking claim. Claims 1-15, 20-30 and 34-40 are currently under examination as they are drawn to a method of making a genetically modified cell.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 28, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The nucleotide sequence disclosure contained in this application complies with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

The amendments to the specification and the supporting CFR and sequence listing have addressed the basis of the objection. See also Applicants' amendment page 12 of 14 for supporting statement by the attorney.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, 20-30 and 34 stand rejected and new claims 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Stice *et al.* (US Patent 5,945,577).

Applicants review the teaching of Stice *et al.*, noting that Stice *et al.* specifically teach to enucleate the recipient cell *i.e.* the oocyte before insertion of the donor cell. Applicants argue that the present claim explicitly indicate that the donor cell is introduced before the recipient cell is enucleated. Applicants argue that by leaving reprogramming elements associated with the recipient cell, the instantly claimed invention allows for reprogramming of the donor material. See Applicants' amendment, pages 12-13.

Initially, upon review of the instant specification, there is no specific disclosure of the elements required for reprogramming a donor cell, and speculates that leaving the nuclear material in the recipient may be "potentially less disruptive" (see page 2 for example). There is no teaching nor evidence that the method as argued provides for a better re-programming of a cell. As summarized previously, the present specification indicates that the basis of the claimed invention is allowing the recipient nuclear material to be maintained when the donor cell/nuclei is added, and provides no other new guidance that was not known in the art for nuclear transfer

(for example page 2, lines 14-21). Applicants have not addressed the Examiner's review of the present specification. Furthermore, with respect to the breadth of practicing the claims, it was noted that one means of practicing the claimed invention is by pre-treatment through the use of chemical that damage the recipient chromosomes (for example page 6). While in the art this is considered enucleation by chemical means, this accomplishes and anticipates the claims. The instant method simply claims a method of nuclear transfer where the recipient cell is not first enucleated. Stice *et al.* teach methods of nuclear transfer and that one means of enucleating the cell is by chemical means, which is practiced prior to the addition of the donor cell. This is the same methodology taught in the instant specification. Applicants' arguments have been fully considered, but not found persuasive because the instant specification provides the same guidance as that found in Stice *et al.* It is also noted that the instant claims do not specifically state how a diploid cell is produced, only that it is generated, and the use of methods of chemical enucleation do result ultimately in a diploid cell. Arguments regarding the specification providing details to re-programming factors and arguments that the methods of Stice *et al.* provide different results do not appear to be supported by the instant disclosure.

With respect to dependent method claims setting forth the use of various cell types, and further method steps where the resulting reprogrammed cell is allowed to develop into an embryo or differentiate into a specific cell type, Applicants do not argue that this is not taught by Stice *et al.*

Claims 24-29 stand rejected and new claims 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Munsie *et al.* (Reprod. Fertil Dev, 1998).

Applicants argue that the methods of Munsie *et al.* (and that of Stice *et al.*) fail to teach the methods disclosed. See Applicants' amendment pages 13-14.

It is noted that rejection is being made over the products, ant that it was argued that a product by process must be given its reasonably broadest interpretation. In this case, neither the present specification, Applicants' arguments nor the art of record provide a basis for why a resulting animal would be any different based on the methods used to produce said animal. In this case it is noted, that even a wild type animal and/or cell line anticipate the instant claims because the methods do not provide any functional or structural difference to the resulting product. It was noted that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). In this case, Applicants arguments focus on the difference in the methods without detailing why the claimed products would be functionally or structurally distinguishable from that disclosed in the art.

As stated previously, Munsie *et al.* disclose methods methods where chimeric transgenic mice are produced. In the generation and characterization of the mice, cell lines and embryos are used to generate intact animals which contain tissues and organs. In this case any cell, cell line,

tissue, organ or whole animal would be anticipated by any of these produced by any method, even simple methods of isolation because the resulting product, *i.e.* cell, cell line, tissue, organ or animal produced by any means can not be distinguished by the methods used to obtain it.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach